EXHIBIT C

Report Regarding the Ethicon TVT Incontinence Sling

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This report contains a statement of my opinions regarding the Gynecare TVT device. My opinions are based on my education, training, experience, and review of the relevant medical literature and other materials I have obtained or have been provided. A list of the materials I have reviewed is attached to this report. I hold all of my opinions to a reasonable degree of medical and scientific certainty. If I receive additional information after signing this report, I may form additional opinions or change the opinions set forth in this report.

I. Background

a. Education, Training, and Experience

I received my Bachelor of Arts degree from Saint Olaf College in 1975 with majors in Biology, Chemistry, Latin and Ancient Studies. I attended the Medical College of Wisconsin from 1975 to 1979. Upon graduation, I was awarded the Dyke award in neurology.

I matched to a straight ob/gyn residency program at the University of Minnesota. There, I spent six months doing gynecologic oncology, two months doing high-risk obstetrics, and four months running the labor and delivery units and being first assistant on gynecologic cases. At that time, I was introduced to the Kelly plication for treating stress incontinence. I also learned how to do cystometrograms and evaluate patients for different types of incontinence.

I then became a resident at Tulane University in New Orleans Louisiana. There I learned to perform Marshall-Marchetti-Krantz colposuspensions.

I then spent a year-and-a-half doing Public Health Service. During this time, I ran a family planning and women's health clinic for the County of Fresno in California.

I was then enrolled in the residency program at Kaiser Oakland Hospital. I continue to perform urologic procedures including Kelly plications, sacrocolpopexies, and sacro-spinous ligament uterine suspensions.

I am a fellow of the American College of Obstetricians and Gynecologists, a member of the Fresno-Madera Medical Society, and a Diplomate of the National Board of Medical Examiners. A copy of my curriculum vitae is attached to this report.

I was board certified in obstetrics and gynecology in 1986, and have maintained my board certification on a regular basis since that time.

I have been on the morbidity and mortality committees of the Fresno Community Hospital and the St. Agnes Medical Center. I have also been both a member and a case reviewer for the Medical Review Committee of the Fresno Madera Medical Society. I have been an expert reviewer for the Medical Board of California. Additionally I was a member of the St Agnes IRB in 2015.

b. Clinical Experience & Personal Experience with Stress Urinary Incontinence Treatments

While I received basic training in residency, the majority of what I know about and do to treat incontinence has been obtained after the completion of my residency training. When I started my practice, my surgical treatment of choice for stress urinary incontinence was the open Burch urethropexy. I learned how to do laparoscopic Burch procedures in 1998, but found them to be significantly less successful than the open procedure. In 2000, my partner began training in the use of fascia lata pubovaginal slings. In 2001, my partner and I were trained in the use of the Ethicon TVT device. Suburethral polypropylene mesh slings then became my surgical treatment of choice for SUI. I have been trained in and tried a variety of products including TVT, TVT-Secur, the AMS Retro-Arc, the AMS Mini-arc, the Bard Align system, and the Boston Scientific Advantage sling system.

Currently I use a variety of modalities to treat female incontinence including urge incontinence, stress incontinence, and overflow incontinence. We rely extensively on lifestyle changes including weight loss, dietary avoidance, timed voiding, and pelvic floor exercises. We have the availability of both posterior tibial nerve stimulation and pelvic floor stimulators to help patients achieve their goals in a non-surgical fashion. We also use pessaries as needed for patients who do not wish to have surgery, or who are not surgical candidates, but who do not respond to more conservative treatment. For the patients who wish surgical therapy, I place either TVT, Retro Arc, or Mini-Arc slings as I have found these to be the easiest to use with the best success rates.

c. Teaching & Training Experience Related to Stress Urinary Incontinence

I have had representatives in training observe me in the OR to see how I do the procedures and to ask questions about how I use the product.

I have been designated as a proctor by Gynecare for the TVT system. However, I have not to date proctored any physicians.

d. Litigation Consulting Work

I have not testified in a deposition or a trial as an expert witness in the past last four years. I am being compensated $695 per hour for my time in this matter.

II. Summary of Opinions

During my years of practice, I have used Kelly plication, open and laparoscopic Burch cystourethropexy, and various types of suburethral slings to surgically treat my patients' stress urinary incontinence. Of the slings currently available, the Gynecare TVT has the longest experience, most cases, and best documented results of any available. I have personally found it to be very quick to use (15-20 minute surgeries including time to do the cystourethroscopy), highly effective (~ 90+% in both short- and long-term, with only one re-do in 12 years), low complication rate (no bladder perforations, 3-4 mesh exposures, 4-5 urinary retentions (primarily when first starting the procedure), no transfusions or readmittance to the hospital, with very good patient acceptance and satisfaction. The benefits of using the device far outweigh the risks of using the device. The TVT device is not defective, and the instructions for use accompanying the device are adequate.

III. Stress Urinary Incontinence

a. Definition, Mechanism of Action, and Prevalence

Stress urinary incontinence is defined as the involuntary loss of urine with an increase in intra-abdominal pressure. Coughing, sneezing, lifting, standing, and intercourse can all precipitate the loss of urine in a woman with stress incontinence. It is due to the pelvic floor muscles being too weak to overcome the force of the pressure created on the bladder and urethra by the antecedent event.

Urge incontinence is involuntary loss of urine that occurs with the first sensation or urge to urinate.

Overflow incontinence is a condition that occurs when the bladder over-fills without the sensation of the need to urinate. In this case, the bladder will spontaneously contract and release urine without any sensation of needing to void or any increase in abdominal pressure.

Mixed incontinence is a combination of stress and urge incontinence. Most women with incontinence have a combination of these two types, with one type predominating over the other.

Structural incontinence is incontinence due to abnormal anatomic features such as an aberrant ureter or a fistula between the bladder or the ureter and the vagina or uterus.

Functional incontinence occurs when the patient has a normal urge to void and would in normal circumstances be able to make it to the bathroom without difficulty. However because of disability of the patient or immobility of the patient, or the lack of toilet facilities, the patient is unable to find an appropriate place to void before she spontaneously loses urine.

Nocturnal enuresis is loss of urine which occurs at night and is unrecognized until the patient awakens. It may be due to medications, drugs or alcohol, or dreaming.

Giggle or gelastic incontinence is an involuntary response to laughter. It usually affects children. Post-void dribbling or dipuria is the phenomenon where urine remaining in the urethra or bladder after voiding the bladder slowly leaks out after urination. It is often related to the presence of a cystocele.

Coital incontinence (CI) is urinary leakage that occurs during either penetration or orgasm and can occur with a sexual partner or with masturbation. It has been reported to occur in 10% to 24% of sexually active women with pelvic floor disorders.

The prevalence of urinary incontinence in middle-aged and older women has been estimated at 30 to 60% with the percentage increasing with age. According to the CDC, nearly 50% of women age 65 and older have urinary incontinence. It is estimated that 43-77% of nursing home patients suffer from incontinence. Prevalence of urinary incontinence and associated risk factors in nursing home residents: a systematic review.[1]

Stress urinary occurs as a result of weakening of the pelvic floor muscles and supporting tissues and weakening or incompetence of the urethral sphincter. With an increase in intra-abdominal pressure, there is increased pressure on the bladder. The continent patient has a resting tone of the pelvic floor musculature and ligaments that resist spontaneous opening of the urethra at the same time. The incontinent patient does not have sufficient tone or strength in order to resist the increased abdominal pressure and uncontrolled release of urine occurs.

b. Risk Factors for Stress Urinary Incontinence

Risk factors for stress urinary incontinence include increasing age, loss of estrogen due to menopause or castration, being Caucasian or Hispanic, being overweight, smoking, chronic cough, repetitive lifting, pregnancy and childbirth with increased risk with short labors, long labors, or large babies, and vaginal tears, nerve injuries to lower back, a history of pelvic surgery, or a history of muscular atrophy of the pelvis due to neurologic conditions such as polio.

Stress incontinence is more prevalent in women of Caucasian or Hispanic origin who tend to have gynecoid pelvises with an increased pubic angle versus women of African origin who tend

[1] Offermans MP, et al., Prevalence of urinary incontinence and associated risk factors in nursing home residents: a systematic review. Neurourol Urodyn 2009;28(4):288–94.

to have anthropoid pelvises with narrow pubic angles. Patients having genetic collagen abnormalities such as Ehlers-Danlos Syndrome are also more likely to have weakening of the normal pelvic and urethral supports.

c. Economic Impact and Impact on Quality of Life

In the year 2000 the cost of incontinence in those 65 or older was estimated at 19.5 billion dollars.[2]

Having stress incontinence can have a significant negative impact on a woman's life. Because the loss of urine can occur so rapidly with an unexpected sneeze or cough, most women will wear a pad. They start avoiding activities which could cause them to lose urine including any type of exercise. They restrict their fluid intake so that if they do lose urine there is less of it to lose. Occasionally despite their best efforts, women will publicly lose urine leading to great embarrassment. Loss of urine with intercourse can cause them to avoid having sex in order to not be embarrassed and to avoid the necessity of cleaning their clothes and bed clothing after intercourse. Wearing a pad on a continuous basis can cause chaffing of the vulva, an increase in vaginal infections, and unacceptable odor from urine.

Some women will become housebound because of their fear of losing urine in a public place. This obviously restricts their ability to care for themselves and their families or to engage in any type of career that requires them to be in public.

IV. Treatment Options for Stress Urinary Incontinence

a. Non-surgical Treatment Options

When the patient is diagnosed with stress urinary incontinence, a number of nonsurgical options are available. First and foremost, the patient should be taught to do Kegel exercises. These exercises consist of contracting the pelvic musculature repeatedly for up to 200 times a day. Doing these exercises requires a 12-week timeframe to gain maximum effect. For patients who have difficulty determining which muscles to contract, pelvic floor stimulation and training can be undertaken at a physician's office. The patient can undergo lifestyle changes including diet modification, weight loss, avoidance of those things which cause her to lose urine, better control of chronic cough or allergies, and ceasing smoking. The patient may need to change her occupation or hobbies if they involve repetitive or heavy lifting or pulling.

There are a number of urethral inserts or vaginal inserts or pessaries which can be used to occlude or partially occlude the urethra to enable the woman to maintain her normal activities.

[2] Centers for Disease Control, "Prevalence of Incontinence Among Older Americans" Vital and Health Statistics, Series 3, No 36, June 2014.

Topical estrogen may be of use to women as it will increase blood flow to the vulvar musculature and increase the thickness of the mucosa of the vagina.

Non-surgical methods can be effective enough that patients no longer feel the need for surgery. They require daily use of devices or exercises, as well as the will to not return to those habits which contributed to the incontinence in the first place. The vast majority of these women will continue to experience some degree of stress incontinence, though it may be at a level acceptable to the patient.

b. Surgical Treatment Options

In the late 1800s urethral torsion procedures were developed to help treat stress incontinence. It wasn't until 1900 that Howard Kelly developed the Kelly plication method, in which an anterior colporrhaphy was performed and the bladder neck plicated with deep mattress sutures. This operation became the standard of care for female stress urinary incontinence until the 1960s. Over the next several decades following Dr. Kelly's development, various trans-abdominal pubo-vaginal sling operations were developed using the pyramidalis muscle with or without its overlying fascia. In 1942, this procedure was modified to use strips of rectus fascia, which were than attached to the rectus muscle forming a sling under the urethra. Doctors Marshall, Marchetti, and Krantz developed retropubic colposuspension in 1949. In 1961, this was further modified by Dr. Burch, who utilized Cooper's ligament instead of the retropubic periosteum.

Dr. Pereyra developed needle vaginal suspension in 1959. This was further developed by Dr. Stamey under cystoscopic control in 1973.

During this time, peri-urethral bulking agents were also explored using such substances as paraffin, or cod liver oil. Silicone was eventually utilized in the 1990s. The agents are injected between the midurethra and the bladder neck just under the mucosa, partially occluding the urethra while still allowing for the passage of urine. Frequently, patients having these procedures will need to self-catheterize to completely empty the bladder. Currently available agents include autologous fat, glutaraldehyde cross-linked bovine collagen, calcium hydroxylapatite, pyrolytic carbon-coated beads, polydimethylsiloxane, ethylene vinyl alcohol copolymer, and polytetrafluoroethylene. Bulking agents need to be reintroduced on a periodic basis, with the procedure needing to be repeated generally every 4 to 12 months. Peri-urethral bulking agents are a good option for patients who are elderly, frail, who decline a more invasive surgical option, wish to have more children, or who are not good surgical candidates.

Artificial sphincters are used primarily for post-radical prostatectomy incontinence. The rate of complete continence following their placement is approximately 20-30%, with another 50% of patients having minimal loss of urine (a few drops a day). The procedure is rarely used for women with stress incontinence, but may be useful for those female patients who are completely incontinent of urine. They can be challenging to maintain in long-term use.

i. Mid-Urethral Tension-Free Slings

The concept of placing a synthetic mesh sling in a tension-free manner at the mid-urethra was developed by a surgeon named Ulf Ulmsten in Sweden in the mid-1990s in an effort to treat incontinence through a less morbid surgery with more predictable efficacy. The slings generally consist of a small strip of polypropylene mesh tape that is implanted through a small vaginal incision at the level of the mid-urethra rather than the bladder neck, thereby providing support for the mid-urethra during moments of increased bladder pressure caused by coughing, sneezing, or other physical activity.[3] They are used to treat stress urinary incontinence (SUI) with hypermobility of the urethra, SUI with intrinsic sphincter deficiency, mixed incontinence with stress predominance, and recurrent SUI following failed previous procedures. Midurethral sling procedures are minimally invasive, and much less morbid than traditional anti-incontinence procedures such as the Burch procedure or pubovaginal slings. Midurethral sling procedures can be performed via either a retropubic approach or a transobturator approach, but the original procedure developed by Ulmsten utilized a retropubic approach.

Synthetic mesh midurethral slings are the most extensively researched surgical treatment for SUI, and are now the most commonly performed surgery to treat SUI in women.[4] As discussed in greater detail below, they have a good safety profile,[5] and the evidence supporting the use of midurethral slings is of high quality.[6] Indeed, midurethral slings have been called the "new gold standard first line surgical treatment for women with SUI…."[7] Because of the excellent efficacy and safety of midurethral sling procedures, most surgeons have moved to various types of vaginal sling surgery over the past ten years.[8] They are considered to be first line surgical therapy for stress incontinence by both the American Congress of Obstetrics and Gynecology and by the American Urogynecologic Society.

All surgical treatments for incontinence have similar risks. They all present a risk of infection, recurrence of incontinence, bleeding, voiding dysfunction including overactive bladder symptoms and urinary retention, chronic pain, dyspareunia, injury to the vagina/urethra/bladder/ureters/pelvic blood vessels/pelvic nerves/bowel/pubic bone, and

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[3] Petros P and Ulmsten U, An Integral Theory of Female Urinary Incontinence – Experimental and clinical considerations. Acta Obstet Gynecol Scand 1990;69 Suppl 153:7-31.

[4] Schimpf MO, et al., Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. Am J Obstet Gynecol 2014;210:1.e1.

[5] Ford AA, Rogerson L, Cody JD, Ogah J. Mid-urethral sling operations for stress urinary incontinence in women. Cochrane Database of Systematic Reviews 2015, Issue 7. Art. No.: CD006375. DOI: 10.1002/14651858.CD006375.pub3.

[6] Schimpf MO, et al., Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. Am J Obstet Gynecol 2014;210:1.e1.

[7] Cox A, Herschorn S, Lee L, Surgical management of female SUI: is there a gold standard? Nature 2013;10:78-89.

[8] IUGA Stress Urinary Incontinence – A Guide for Women (2011); Chughtai BI, et al., Midurethral Sling Is the Dominant Procedure for Female Stress Urinary Incontinence: Analysis of Case Logs From Certifying American Urologists. Urology 2013 Dec;82(6):1267-71; Clemons JL, et al., Impact of the 2011 FDA Transvaginal Mesh Safety Update on AUGS Members' Use of Synthetic Mesh and Biologic Grafts in Pelvic Reconstructive Surgery. Female Pelvic Med Reconstr Surg 2013;19:191-98; .

wound healing complications. Synthetic mesh erosion is unique to surgeries that utilize mesh, but it should be noted that non-absorbable sutures can erode through surrounding tissues. The complications following all of these surgeries can be temporary or permanent, and can range from mild to severe. All surgical treatments include the potential need for reoperation to address complications.

V. Ethicon TVT Products

a. Historical Background of Surgical Use of Mesh

Prolene polypropylene suture, first introduced by Ethicon in 1969, is a non-absorbable, sterile surgical suture. Polypropylene suture is commonly used in both human and veterinary medicine for skin closure, Cardiovascular, Ophthalmologic, General Closure, Orthopedics, Plastic and Microsurgeries, soft tissue approximation and/or ligation. As it is a monofilament suture, it does not support bacterial growth. It is not affected by blood, or weakened by tissue enzymes. It offers prolonged tensile strength, even in infected areas, as it is not degraded over time. This suture has a smooth texture and is known for low tissue drag and minimal tissue trauma, easy handling and good strength. It is highly plastic and has a uniform diameter, with high tensile strength, resisting breakage. Polypropylene sutures are normally available in blue color, allowing for easy identification and better visibility against skin when operating.

The first polypropylene mesh was introduced in 1958 as Marlex mesh. It revolutionized hernia surgery by reinforcing and replacing the weakened or absent fascial tissues that allow hernias to form. In the mid-1960s the mesh was used for open sacrocolpopexies. It allows for a solid tensionless support of the vaginal cuff in these procedures. I have used mesh for sacrocolpopexies since my residency. I began using Gynemesh PS to reinforce tissues in anterior colporrhaphies since 2004. Prior to using mesh augmentation approximately 33% of anterior repairs would fail over time (up to 10 years). Currently in my practice the recurrence is less than 10%.

b. The Development of Tension-Free Vaginal Tape Using Prolene Mesh

As noted above, in the mid-1990s, Dr. Ulmsten developed an innovative procedure for treating female SUI. The procedure was based on what Dr. Ulmsten and his colleague Dr. Petros called the "Integral Theory," which suggested that SUI symptoms are due to laxity in the vagina resulting from defects within the vaginal wall or the ligaments, muscles, and connective tissue supporting the vagina. Ulmsten tried a variety of sling materials but found unacceptable rejection rates in materials such as Gore-Tex and Mersilene, so lightweight, large-pore, monofilament, knitted Prolene mesh was chosen as the most suitable mesh material.[9]

[9] Petros P and Ulmsten U, An Integral Theory of Female Urinary Incontinence – Experimental and clinical considerations. Acta Obstet Gynecol Scand 1990;69 Suppl 153:7-31

A representative from Ethicon met with Dr. Ulmsten to learn more about the surgery, and Ethicon ended up purchasing the rights to the sling, which became known as the TVT device.[10]

c. The TVT Device

The TVT device is "a sterile single use device, consisting of one piece of undyed or blue . . . PROLENE® polypropylene mesh (tape) approximately ½ x 18 inches (1.1 x 45 cm), covered by a plastic sheath cut and overlapping in the middle, and held between two stainless steel needles bonded to the mesh and sheath with plastic collars. The Prolene polypropylene mesh is a Type I knitted monofilament, lightweight mesh.[11]

Implantation of the TVT device involves making a small incision under the midurethra and two small suprapubic incisions on the abdomen. The needles/trocars with the mesh attached are then passed through the suburethral incision, passing the mesh through the retropubic space and exiting through the suprapubic abdominal incisions. The mesh is not anchored in place with sutures, but subsequently becomes anchored in place through scar tissue that incorporates into the mesh. The mesh is placed in a tension-free manner. Once the mesh is positioned, the needles/trocars and sheathes are removed and the incisions are closed. The procedure can be performed in as little as 15–20 minutes as an outpatient procedure, and can be done under either local or general anesthesia. Patients are usually discharged within one hour of the procedure and with or without indwelling catheters.

i. The utility and safety of the device.

As noted above, I have personally found the TVT device to be very quick to use, with excellent efficacy and a low rate of complications. I have found the device to be effective in approximately 90+% of patients in both the short- and long-term. I have only had to re-do one TVT in 12 years of using the device. I have never had a bladder perforation. I have had only 3–4 mesh exposures/erosions, and only 4–5 instances of post-operative urine retention (most of which occurred when I first started using the device). None of my TVT patients required a blood transfusion or readmission to the hospital. Patient acceptance and satisfaction with the outcome of their treatment with the TVT device was very good. The benefits of using the device far outweigh the risks of using the device.

My experience using the TVT is consistent with the published in terms of the device's efficacy and safety. The Society of Gynecologic Surgeons Systematic Review Group's systematic review and meta-analysis published in 2014, reports the following adverse event rates for retropubic slings like the TVT:

[10] The history of TVT (Ethicon document).

[11] "Type I" meshes are large-pore meshes containing pores larger than 75 microns, "which is the required pore size for admission of macrophages, fibroblasts (fibroplasia), blood vessels (angiogenesis) and collagen fibers into the pores…." Amid PK, Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia 1997;1:15–21.

Blood loss greater than 200 mL - 1.5%
Need for transfusion - .40%
Hematoma - .88%
Dyspareunia - 0.00%
Return to the operating room for treatment of erosion - 1.9%
Mesh exposure - 1.4%
Wound infection - 0.75%
Urinary tract infection - 11.0%
Bowel injury - 0.34%
Nerve injury - 0.06%
Ureteral injury - 0.00%
Vascular injury - 0.08%
Over-active bladder or urgency - 6.9%
Post-operative urinary retention less lasting less than six weeks - 3.1%
Urinary retention lasting greater than six weeks - 2.7%
Re-operation for urinary retention - 1.2%
Groin pain - 1.5%
Leg pain - 0.62%
Bladder perforation - 3.6%
Urethral perforation - 0.41%
Vaginal perforation - 0.73%
Deep vein thrombosis - 0.06%

The most serious of these complications are bowel injury (0.34%), nerve injury (0.06%), ureteral injury (0.00%), urethral perforation (0.41%), and deep vein thrombosis (0.06%). The other adverse events, while they will cause varying degrees of discomfort to the patient, do not tend to be life-threatening or long-lasting. (See Table 1)

The SGS systematic review and meta-analysis also sets forth the rates of adverse events with the Burch procedure and Pubovaginal slings, which shows that retropubic midurethral slings compare very favorably to those traditional incontinence procedures.

	Burch	**Pubovaginal Sling**
Blood loss greater than 200 mL	Not Reported	Not reported
Need for transfusion	0.00%	1.9%
Hematoma	1.4%	2.2%
Dyspareunia	Not Reported	0.99%
Return to O.R. for treatment of erosion	0.28%	1.6%
Mesh exposure	0.00%	5.4%
Wound infection	7.0%	2.6%
Urinary tract infection	5.9%	4.2%

Bowel injury	3.13%	Not Reported
Nerve injury	Not Reported	Not Reported
Ureteral injury	0.61%	0.18%
Vascular injury	Not Reported	Not Reported
Over-active bladder or urgency	4.3%	8.6%
Post-operative urinary retention less lasting less than six weeks	17%	12%
Urinary retention lasting greater than six weeks	7.6%	7.5%
Re-operation for urinary retention	0.00%	3.0%
Groin pain	1.10%	0.34%
Leg pain	Not Reported	Not Reported
Bladder perforation	2.8%	2.3%
Urethral perforation	0.00%	Not Reported
Vaginal perforation	0.21%	0.00%
Deep vein thrombosis	0.58%	0.35%

A 2015 systematic review and meta-analysis by Tommaselli and colleagues indicated that the vaginal erosion rate with retropubic midurethral slings like the TVT is 2.1%, and the rate of persistent or chronic pain—which the authors defined as pain persisting beyond the perioperative period or reported at the last follow-up visit—was only 0.3%.[12]

A 2015 Cochrane Review of midurethral slings for the treatment of SUI analyzed 81 studies involving a total of 12,113 women. It found that more than 80% of women undergoing a midurethral sling surgery for SUI were cured or had significant improvement in their symptoms for up to five years after surgery. They found moderate quality evidence that overall reported rates of tape-related complications are low, with an erosion rate of about 2% for either retropubic or transobturator tapes. They also found a low rate of problems with sexual intercourse including pain, and that leakage of urine during intercourse improved. At 24-month follow-up, the authors found rates of superficial and deep dyspareunia were low with both retropubic and transobturator midurethral slings.[13]

A 2009 Cochrane review of 62 studies involving 7,101 women showed that retropubic slings like the TVT or transobturator slings like the TVT-O are as effective as traditional suburethral slings, but have shorter operative times and less post-operative voiding dysfunction and de novo urgency symptoms. They also found that midurethral slings were as effective as open

[12] Tommaselli GA, Medium-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: a systematic review and metaanalysis. Int Urogynecol J 2015 Sep;26(9):1253–68.
[13] Ford AA, et al., Mid-urethral sling operations for stress urinary incontinence in women. Cochrane Database Syst Rev. 2015 Jul 1;7:CD006375. Doi: 10.1002/14651858.CD006375.pub3.

retropubic procedures, but with shorter operative times, shorter hospital stays, less peri-operative morbidity (with the exception of a higher rate of bladder perforations) and less post-operative voiding dysfunction.[14] A 2008 systematic review and meta-analysis of randomized controlled trials comparing tension-free midurethral tapes to other surgical procedures and different devices reported a vaginal erosion rate of 1.1% with the TVT device.[15] The low complication rates reported in these studies are consistent with my experience using the TVT sling.

The TVT is the most-studied incontinence surgery, and the studies on the device have the longest follow-up of any incontinence treatment. Those studies have demonstrated high efficacy and low complication rates out to as many as 17 years.[16] Many long- and intermediate-term studies consistently show that the TVT is safe and effective and the standard of care for surgical treatment of SUI.[17]

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[14] Ogah J, et al., Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. Cochrane Database Syst Rev. 2009 Oct 7;(4):CD006375. doi: 10.1002/14651858.

[15] Novara G, et al., Complication Rates of Tension-Free Midurethral Slings in the Treatment of Female Stress Urinary Incontinence: A Systematic Review and Meta-Analysis of Randomized Controlled Trials Comparing Tension-Free Midurethral Tapes to Other Surgical Procedures and Different Devices. Eur Urol 2008;53:288–309.

[16] Nilsson CG, et al., Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J 2013 Aug;24(8):1265–1269. doi 10.1007/s00192-013-2090-2.

[17] Serati M, et al., TVT for the Treatment of Urodynamic Stress Incontinence: Efficacy and Adverse Effects at 13-Year Follow-Up. Neurourol and Urodynamics DOI 10.1002/nau; Laurikainen E, et al., Five-year Results of a Randomized Trial Comparing Retropubic and Transobturator Midurethral Slings for Stress Incontinence. Eur Urol 2014 Jun;65(6):1109–14; Angioli R, et al., Tension-Free Vaginal Tape Versus Transobturator Suburethral Tape: Five-Year Follow-up Results of a Prospective, Randomised Trial. Eur Urol 2010;58:671–677; Heinonen P, et al., Tension-free vaginal tape procedure without preoperative urodynamic examination: long-term outcome. Int J Urol. 2012 Nov;19(11):1003-9; Aigmueller T, et al., Ten-year follow-up after the tension-free vaginal tape procedure. Am J Obstet Gynecol 2011 Nov;205(5):496.e1-5; Olsson I, et al., Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence: a retrospective follow-up 11.5 years post-operatively. Int Urogynecol J 2010 Jun;21(6):679–683; Liapis A, et al., Long-term efficacy of tension-free vaginal tape in the management of stress urinary incontinence in women: efficacy at 5- and 7-year follow-up. Int Urogynecol J 2008 Nov;19(11):1509-1512; Svenningsen R, et al., Long-term follow-up of the retropubic tension-free vaginal tape procedure. Int Urogynecol J. 2013 Aug;24(8):1271-8; Chêne G, et al., Long-term results of tension-free vaginal tape (TVT) for the treatment of female urinary stress incontinence. Eur J Obstet Gynecol Reprod Biol 2007 Sep;134(1):87-94; Vesna Bjelic-Radisic V, Patient-related Outcomes and Urinary Continence Five Years After the Tension-Free Vaginal Tape Operation, Neurourology and Urodynamics 2011;30(8):1512-1517 (2011); Jin-Yan Wu JY, et al., Surgical therapies of female stress urinary incontinence: experience in 228 cases, Int Urogynecol J 2010 Jun;21(6):645-649; Song PH, et al., The 7-year outcome of the tension-free vaginal tape procedure for treating female stress urinary incontinence. BJU Int 2009 Oct;104(8):1113-1117; Kuuva N, et al., Long-term results of the tension-free vaginal tape operation in an unselected group of 129 stress incontinent women. Acta Obstet Gynecol 2006;85(4):482-487; Celebi I, et al., Results of the tension-free vaginal tape procedure for treatment of female stress urinary incontinence: a 5 year follow-up. Arch Gynecol Obstet 2009 Apr;279(4):463-467; Prien-Larsen JC, et al., Long-term outcomes of TVT and IVS operations for treatment of female stress urinary incontinence: monofilament vs. multifilament polypropylene tape. Int Urogynecol J 2009 Jun;20(6):703-709; Jelovsek JE, et al, Randomized trial of laparoscopic Burch colposuspension versus tension-free vaginal tape: long-term follow up. BJOG 2008 Jan;115(2):219-225; McCracken GR, et al., Five Year Follow-up Comparing Tension-Free Vaginal Tape and Colposuspension, Ulster Med J 2007 Sep;76(3):146-149.

Serati published 10-year objective and subjective outcomes following the TVT procedure in a multi-center trial. The authors found that "[t]he 10-year subjective, objective, and urodynamic cure rates were 89.7%, 93.1%, and 91.4% respectively."[18]

The 2014 Laurikainen study reported 5-year results of a multi-center randomized controlled trial of retropubic and transobturator slings, and reported an objective cure rate of 84.7% in the retropubic group, with low complication rates and no late-onset adverse effects from the mesh. There was no sign of tissue reaction, erosion, or tape protrusion at 5-year follow-up.[19]

Svenningsen and colleagues published a study with 10-year follow-up of the initial 603 women included in the Norwegian retropubic midurethral sling registry, and noted that 80% of observed an objective cure rate (negative stress test) of 89.9%, and a subjective cure rate of 76.1%. Repeat SUI surgery was only done in 2.3% of the patients. While de novo over-active bladder increased from 4.1% at 6-12 months to 14.9% at 10 years, a secondary risk analysis found that a severe pre-operative urgency incontinence component and surgical complications represented independent risk factors for long-term failure.[20]

In 2012, Heinonen and colleagues published their study with 10-year follow-up after TVT midurethral sling procedures, and noted an objective cure rate of 90% and a 0.8% rate of mesh erosion into the bladder 1.6% of urinary retention and pain, which resolved with transection of the tape.[21] Olsson and colleagues, in 2010, reported on the 10-year follow-up results of Ulmsten's original multicenter retropubic midurethral sling study, and found an objective success rate of 84%, with no late adverse effects of the operation.[22]

The TVT device works well in a large variety of patients, including obese patients. That is important, as obesity is commonly a comorbidity with SUI. Studies have shown that the TVT's success rate in non-obese women is not significantly different than its success rate in obese women.[23]

Many professional societies and organizations have issued statements supporting the use of synthetic mesh midurethral slings. The American Urogynecological Society (AUGS) and the

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[18] Serati M, et al., Tension-free Vaginal Tape for the Treatment of Urodynamic Stress Incontinence: Efficacy and Adverse Effects at 10-Year Follow-Up. Eur Urol 2012;61:939–46.

[19] Laurikainen E, et al., Five-year Results of a Randomized Trial Comparing Retropubic and Transobturator Midurethral Slings for Stress Incontinence. Eur Urol 2014 Jun;65(6):1109–14.

[20] Svenningsen R, et al., Long-term follow-up of the retropubic tension-free vaginal tape procedure. Int Urogynecol J. 2013 Aug;24(8):1271-8.

[21] Heinonen P, et al., Tension-free vaginal tape procedure without preoperative urodynamic examination: long-term outcome. Int J Urol. 2012 Nov;19(11):1003-9.

[22] Olsson I, et al., Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence: a retrospective follow-up 11.5 years post-operatively. Int Urogynecol J 2010 Jun;21(6):679–683.

[23] Osborn DJ, Obesity and Female Stress Urinary Incontinence, Urol 2013;82:756–63; Greer WJ, Obesity and Pelvic Floor Disorders: A Review of Literature, Obstet Gynecol 2008 Aug;112(2 Pt 1):341–9; Revicky V, et al., Obesity and the Incidence of Bladder Injury and Urinary Retention Following Tension-Free Vaginal Tape Procedure: Retrospective Cohort Study. Obstet Gynecol Int 2011;2011:746393. doi: 10.1155/2011/746393. Epub 2011 Jun 22.

Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) have said that "[t]he polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for millions of women." Those organizations have also noted that "[a] broad evidence base including high quality scientific papers in medical journals in the US and the world supports the use of the MUS as a treatment for SUI. There are greater than 2000 publications in the scientific literature describing the MUS in the treatment of SUI. These studies include the highest level of scientific evidence in the peer reviewed scientific literature." They have said that the synthetic mesh midurethral sling procedure "is probably the most important advancement in the treatment of stress urinary incontinence in the last 50 years and has the full support of our organizations which are dedicated to improving the lives of women with urinary incontinence."[24] AUGS has also said that "[f]ull-length midurethral slings, both retropubic and transobturator, have been extensively studied, are safe and effective relative to other treatment options and remain the leading treatment option and current gold standard of care for stress incontinence surgery."

The American Urological Association has issued a position statement that provides:

> "Extensive data exist to support the use of synthetic polypropylene mesh suburethral slings for the treatment of female SUI, with minimal morbidity compared with alternative surgeries. Advantages include shorter operative time/anesthetic need, reduced surgical pain, reduced hospitalization, and reduced voiding dysfunction. Mesh-related complications can occur following polypropylene sling placement, but the rate of these complications is acceptably low. Furthermore, it is important to recognize that many sling-related complications are not unique to mesh surgeries and are known to occur with non-mesh sling procedures as well. It is the AUA's opinion that any restriction of the use of synthetic polypropylene mesh suburethral slings would be a disservice to women who choose surgical correction of SUI."[25]

The National Institute for Health Care Excellence issued a clinical guideline regarding treatment of urinary incontinence in women, which states that surgeons should "use procedures and devices for which there is current high quality evidence of efficacy and safety" when deciding which synthetic midurethral slings to offer a patient. NICE then specifically lists Ethicon's TVT and TVT-O slings as two of the devices for which there is currently high quality evidence of efficacy and safety.[26] The International Continence Society has noted that, "[w]orldwide, midurethral slings comprised of synthetic mesh have become the treatment of choice for SUI. Long-term data are robust and demonstrate durable efficacy with a very low complication rate, particularly in experienced hands."

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[24] AUGS-SUFU Position Statement on Mesh Midurethral Slings for SUI, 2014 Jan.

[25] AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence, 2011.

[26] National Institute for Health and Care Excellence, Urinary incontinence: The management of urinary incontinence in women, Sept. 2013 at guidance.nice.org.uk/cg171.

As recently as November 2015, the American College of Obstetricians and Gynecologists (ACOG) and AUGS issued a practice bulleting discussing clinical management guidelines for OB-GYNs on urinary incontinence. ACOG and AUGS noted that "[s]ynthetic midurethral slings demonstrate efficacy that is similar to traditional suburethral fascial slings, open colposuspension, and laparoscopic colposuspension," but with fewer adverse events than pubovaginal slings and less voiding dysfunction than the open Burch colposuspension. The organizations noted that, "midurethral synthetic mesh slings have become the primary surgical treatment for stress urinary incontinence in women."[27]

At this point in time there is no other device, medication, or therapy which has the same ease-of-use, low-cost, low morbidity and mortality, and high efficacy both in the immediate postoperative period and over time.

Plaintiffs' experts often suggest that a plaintiff's complications would have been avoided had the plaintiff had an alternative procedure such as the Burch procedure or a pubovaginal sling. But those traditional procedures share the same potential complications as the TVT procedure, with the exception of mesh exposure/erosion. And as the literature cited above makes clear, the efficacy and complication rates with the TVT device compare favorably to those traditional procedures, and are often more favorable than the rates associated with the traditional procedures. And the TVT procedure is a much less morbid procedure than the Burch procedure or the pubovaginal sling procedure. Reported efficacy rates for the Burch procedure and pubovaginal sling procedures vary, but have been reported to be as low as 19–38% for the Burch procedure.[28] A Cochrane review studying TVT outcomes versus Burch outcomes showed that TVT had fewer complications than Burch, less voiding dysfunction, higher safety, and shorter operative times, and was as effective.[29] A 2010 meta-analysis showed that patients receiving midurethral tapes—especially the TVT—had significantly higher overall and objective cure rates than those receiving the Burch procedure. The midurethral sling patients did, however, have a higher risk of bladder perforation.[30] Re-operation following a Burch procedure is more invasive, difficult, and costly. For instance, if a Burch is over tightened, the abdominal incision needs to be reopened and one of the sutures cut. Generally this would occur no sooner than 12 weeks post-operatively. It would require another stay in the hospital and an additional 2-4 weeks off work. In comparison, an overtightened TVT can be loosened in the office with local anesthetic gel in a matter of minutes. It requires no additional recovery time and can be done easily up to six weeks postoperatively. If the retention occurs later than 6 weeks or if a

[27] ACOG & AUGS, Practice Bulletin No. 155, 2015 Nov.

[28] Kjolhede P, Long-term efficacy of Burch colposuspension: a 14-year follow-up study. Acta Obstet Gynecol Scand 20205;84:767–72; Albo ME, et al., Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence. N Engl J Med. 2007 May 24;356(21):2144–55.

[29] Ogah J, et al., Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. Cochrane Database of Systematic Reviews 2009;4:CD006375. DOI:10.1002/14651848.CD006375.pub2.

[30] Novara G, et al., Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. Eur Urol 2010 Aug;58(2):218–38.

simple loosening does not work, a short outpatient procedure can be done to simply incise the TVT in the midline giving it a release of 1 to 3 mm which is usually sufficient to relieve retention while maintaining continence.

Plaintiffs' experts also contend that alternative mesh materials such as Ultrapro, Vypro, Gynemesh PS, or other larger-pore, lighter-weight meshes would have reduced the plaintiff's risk of complications. However, there is no peer-reviewed published data showing the feasibility of the use of those meshes in the context of an SUI sling. The Okulu study of the use of Vypro, Ultrapro, and Gynemesh PS in the context of an SUI surgery utilized a procedure that was very different from the TVT procedure. Also, the study showed that complications like urine retention, continued incontinence, de novo urgency, and vaginal erosions occurred in each of the patient cohorts. Studies have shown Vypro to be poorly tolerated in the context of pelvic floor surgery. The Prolene mesh used in the TVT product is the most studied mesh used in incontinence surgery and has the most safety and efficacy data supporting it. Monofilament meshes like the mesh in the TVT device have been shown to have significantly higher objective cure rates compared to multifilament tapes, and fewer mesh erosions than multifilament tapes.[31]

Xenograft slings made from animal tissue or allograft slings made from cadaveric tissue are available alternatives to mesh slings, but those materials have drawbacks that mesh does not have. Both xenograft and allograft materials can transmit diseases, they are costly, they can be difficult to work with, and they are sometimes met with religious or cultural objections by women who do not want animal or cadaver tissue implanted in them. Synthetic mesh is readily available, does not transmit disease, is easy to work with, and is widely accepted by patients.

Ethicon initially produced the TVT slings with mechanically cut mesh, but made laser-cut mesh available in 2006. I have used both mechanically cut mesh slings and laser-cut mesh slings, and have seen no clinically significant difference between the two. Nor have I seen any clinically significant difference between the two meshes set forth in the published medical literature. Rather, studies from before 2006 and after 2006 both show consistent and strong efficacy and safety in the slings. In my opinion, both laser-cut and mechanically cut mesh is safe and effective.

Plaintiffs' expert witnesses have contended that mechanically cut TVT mesh loses particles, which causes adverse effects in patients. In more than 250 uses of the TVT devices in my career, I have not seen any clinically significant particle loss in my patients. Even if it were the case that the mesh lost particles in the patient, the particles lost would be the Prolene polypropylene suture material that has been safely and effectively used in millions of patients over the course of many decades.

[31] Ogah J, et al., Minimally Invasive Synthetic Suburethral Sling Operations for Stress Urinary Incontinence in Women: A Short Version Cochrane Review. Neurourol and Urodyn 2011;30:284–91.

Plaintiffs' expert witnesses have also claimed that TVT mesh ropes, curls, contracts, and degrades in the patient's body. When the mesh is properly implanted as set forth in the IFU and as explained in Ethicon's professional education seminars and publications, roping or curling of the mesh are not an issue. As far as degradation is concerned, again, I have not seen clinically significant degradation of the TVT mesh in my practice, nor have I seen clinically significant degradation described in the published literature, even in those patients on whom I re-operated following a prior midurethral sling procedure. If the TVT device degraded as plaintiffs' witnesses claim, one would not see the excellent long-term efficacy and safety shown in the published medical literature. The Clave study often relied on by plaintiffs' witnesses in support of their degradation contention does not, in my opinion, reliably show degradation. The authors analyzed less than 1/3 of the overall samples, and did not describe why that limited subset was analyzed. The surface cracking shown on the scanning electron microscope (SEM) images may be due to handling, preparation for SEM analysis, or from biologic material. It also appears that the chemical analyses performed did not show degradation.[32]

Plaintiffs' experts claim the TVT mesh is heavyweight, small-pore mesh. I disagree. While there are meshes that have larger pores and are lighter weight than the TVT mesh, that does not mean the TVT mesh is not lightweight and large-pore. The TVT mesh is among the SUI meshes with the largest pore size. The pores are 1,379 microns across. They are large enough that one can see through them very easily with the naked eye. The pores are large enough to allow excellent tissue ingrowth as well as the passage of leukocytes and macrophages, which are less than 20 microns, to clear any bacteria present. Woven meshes and multifilament meshes—as opposed to knitted meshes like the TVT mesh—can have interstices that are less than 10 microns, and can pose a greater risk of infection.

Plaintiffs' expert witnesses also contend that implanting mesh transvaginally violates fundamental surgical precepts because it introduces a foreign body implanted through a non-sterile field. I disagree. The vagina can be easily and effectively surgically prepped to minimize the chance of infection. This is evidenced by the fact the low infection rates seen with midurethral sling procedures, which are much lower than the rates of wound infection seen with the Burch procedure or pubovaginal sling procedures.[33]

Plaintiffs' expert witnesses have also suggested that the polypropylene used in the TVT device is carcinogenic. I am unaware of a single report of cancer following implantation of any midurethral sling. Published literature refutes this contention by the plaintiffs' witnesses.[34]

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[32] Clavé A, et al., Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. Int Urogynecol J 2010;21:261–70.

[33] Schimpf MO, et al., Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. Am J Obstet Gynecol 2014;210:1.e1.

[34] AUGS & SUFU, Frequently Asked Questions by Providers—Mid-urethral Slings for Stress Urinary Incontinence. (available at http://www.augs.org/p/bl/et/blogaid=194); King A, et al, Current Controversies Regarding Oncologic Risk Associated with Polypropylene Midurethral Slings. Curr Urol Rep 2014;15:453; Moalli P, et al., Polypropylene mesh: evidence for lack of carcinogenicity. Int Urogynecol J 2014, DOI 10.1007/s00192-014-2343-8.

When used in the manner prescribed by the manufacturer as set forth in the IFU and as taught in Ethicon's professional education, TVT is very safe and has a low complication rate. Important considerations include proper patient selection, patient positioning on the table with the hips flexed at no more than 60°, use of some type of mark no more than 2 centimeters off midline in the suprapubic region to assure an appropriate target for passing the needles, use of hydrodissection of a minimum of 30-50 mL of a dilute local anesthetic solution on each side of the urethra, full-thickness incision through the vaginal mucosa 1 cm from the urethral meatus, use of the urethral guide to deflect the bladder to the contralateral side during the needle passage, immediate cystoscopy, and proper placement without tension and proper spacing of the sling from the urethra.

The instructions and warnings set forth in the IFU are adequate in my opinion. The IFU begins with a request to the user to "[p]lease read all information carefully."[35]

VI. The TVT's Instructions for Use and Other Educational Materials

a. Ethicon's Instructions for Use (IFU)

All TVT kits come with an IFU pamphlet describing the product and its proper placement. Additional materials are available online or through the TVT sales rep. These materials are kept up to date reflecting continuing research, results and modifications of the product. It cautions that the IFU "is not a comprehensive reference to surgical technique for correcting Stress Urinary Incontinence (SUI). The device should be used only by physicians trained in the surgical treatment of Stress Urinary Incontinence and specifically in implanting the GYNECARE TVT device." It also cautions that "[v]ariations in use may occur in specific procedures due to individual technique and patient anatomy."

The IFU goes on to describe the indications for the use of the device, as well as contraindications. It provides detailed instructions for using the device. The IFU contains a "WARNINGS AND PRECAUTIONS" section that advises that users of the device "should be familiar with surgical technique for bladder neck suspensions and should be adequately trained in implanting the GYNECARE TVT system before employing the GYNECARE TVT device. It is important to recognize that GYNECARE TVT is different from a traditional sling procedure in that the tape should be located without tension under the mid-urethra."

The IFU warns that "[a]cceptable surgical practice should be followed for the GYNECARE TVT procedure as well as for the management of contaminated or infected wounds." It also warns that "[t]he GYNECARE TVT procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of needles will minimize risks."

[35] ETH.MESH.02340504-67.

The IFU also contains an "ADVERSE REACTIONS" section that warns that "[p]unctures or lacerations of vessels, nerves, bladder or bowel may occur during needles passage and may require surgical repair." The section also warns that "[t]ransitory local irritation at the wound site and a transitory foreign body response may occur," and that it "could result in extrusion, erosion, fistula formation and inflammation." It also warns that over-tensioning of the mesh "may cause temporary or permanent lower urinary tract obstruction."

Plaintiffs' experts contend the IFU is inadequate because it does not warn of pain or dyspareunia, or because it does not set forth the severity, frequency, or duration of the adverse events that can occur. However, surgeons know that all pelvic floor surgery involves a risk of pain, dyspareunia, recurrence of incontinence, re-operation, infection, wound healing complications, etc. And surgeons know that those adverse events or any others could be temporary or they could be permanent. And they could be mild, moderate, or severe. In my opinion it was and is wholly unnecessary for the IFU to warn of those things. While mesh erosion is a unique complication for mesh-related surgeries, surgeons are well aware of how the body reacts to polypropylene mesh and that erosions are possible.

The vast majority of surgeons who perform sub-urethral slings have been trained in residency, fellowship or post-graduate courses. Individual privileges for performing sub-urethral slings and cystoscopy are part of the credentialing process and within the purview of the medical staff of the institution where the procedure is to be performed.

In 2008 the FDA sent out a warning to healthcare providers notifying them of the possible complications arising from use of synthetic meshes for vaginal repair or for the treatment of incontinence. The Public Health Notification indicated that "[t]he most frequent complications included erosion through the vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence." It also indicated that "[t]here were also reports of bowel, bladder, and blood vessel perforation during insertion. In some cases, vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia." The notification then provided recommendations regarding risk discussions that surgeons should have with patients to inform them about the procedure and the potential risks associated with the procedure. It also suggested that the surgeons provide patients with a written copy of the patient labeling from the mesh manufacturer, if available.

Additional warning letters were sent to healthcare providers in 2011 and in 2014. Following the FDA notifications, the lay press had multiple articles about the complications, followed by law firms advertising on TV, the Internet, newspapers, and magazines for patients who had had any type of implantable mesh. A basic internet search for mesh complications yield tens of thousands of results. It would be impossible to be a pelvic floor surgeon present in modern American society and not be aware that questions have been raised about the potential complications of mesh implants in vaginal and urologic surgery.

Ethicon also has a wide variety of provider informational materials and support available. They offer training assistance with proctoring and both cadaver and pelvic model labs to educate surgeons who wish to perform the procedure. These various methods of training stress correct application of the product, strategies to avoid injuries and complications, and instructions for management of potential complications.

a. Ethicon's Brochures

I always give my patients a copy of the written patient materials provided by Ethicon regarding the TVT. They not only provide a visual guide to the procedure but also provide a comprehensive, easily understandable review of incontinence, its various causes, a variety of non-surgical management strategies, and a complete disclosure of the potential risks in layman's terms. The information contained in it is nearly identical to the information we give patients for their formal written consent. Ethicon also provides a website where patients can get additional information and see animated videos of the product.
Despite the completeness of the patient materials, it is not intended to be a substitute for a personal review of the risks and benefits between a surgeon and patient within an open atmosphere and with the patient being encouraged to ask any questions and receive sufficient information to feel comfortable with her knowledge prior to consenting to the procedure. This informed consent process is required by both law and good medical practice.

b. Ethicon's Training Programs

Ethicon's professional education program supplements the IFU. Ethicon's training programs include a didactic session regarding stress incontinence, the development of the TVT, its efficacy in the short and long term, indications and contraindications for use, how to properly place the TVT, possible complications and how to avoid and manage them. Following the didactic session, pelvic models are used to help surgeons see where and how to pass the needles and place the mesh. Cadaver training is also used to help surgeons acquire a feel for the passage of the needles through the tissue planes and to directly observe to adjacent structures to help the determine strategies to avoid injuring them.

When the trainee is ready to perform their first cases, Ethicon will provide a proctor to review the procedure with the trainee, come into the OR to assure that the setup is correct, supervise the procedure step-by-step, and answer any questions that arise. Many proctors are also available by phone should the trainees have any questions in the future or wish to discuss any cases or complications.

Once the training session is complete, documentation of attending the course is provided by Ethicon. This documentation is neutral regarding the surgeon's level of skill or competence to perform the procedure. Credentialing the surgeon to perform the procedure is solely under the purview of the medical staff of the surgeon's hospital. They determine if proctoring is required, who is allowed to do the proctoring, and how many cases need to be done before proctoring is no longer required.

Dated: February 29, 2016

Cynthia Bergmann, M.D.

Table 1
Comparison of Different Surgical Treatments of Stress Incontinence

	Kelly* (with anterior repair)	Burch	Laparoscopic Burch	Pubo-vaginal sling	TVT	TOT
Indication	SUI	SUI	SUI	SUI	SUI	SUI
Skill Level required	++/+++	++++	++++	++++	++	++
Inpatient/outpatient	Inpatient	Inpatient	Outpatient	Inpatient	Outpatient	Outpatient
Length of operation	30-45	60-90	120-180	60	30	30
Length and location of incision	6 cm - vagina	16 cm - abdomen	.5 cm x2, 1 cm x 1 - abdominal	10 cm abdominal 6 cm vaginal	.3 cm x2 abdominal 1.5 cm vaginal	.3 cm x 2 groin – 1.5 cm vaginal
Transfusion		0-7.7%		0.9-3.2%	0.28-0.55%	0.02-1.22%
Retention>6 weeks	43.3%(1)	4.7-11%		5.4-10%	2.1-3.4%	1.4-3.6%
Days in hospital	1-2	1-2	0	1-2	0	0
Cost	+++	++++	+++	+++	++	++
Time off work	6 weeks	6 weeks	1-2 weeks	2-4 weeks	1-2 weeks	1-2 weeks
Success rate- immediate	80% (4)	71% (2) 38% - 2 years (9)	89% (3)	82%(5) 47% - 2 years (9)	85%	86.7% (4)
Success rate – long term	66% - 3 years 55% - 5 years(1)	52% - 3 years(2) 19% - 14 years (8)	68% - 3 years (3)	76%/52% 1°/2° 7 years(6)	70% - 7 yrs	59.6%(7) 8 years

[This is not a head-to-head comparison, but a compilation of information about different methods.]
*Kelly plications are most usually done as part of a native tissue anterior repair with or without hysterectomy which necessitates an in hospital stay.
Obstetrics and Gynecology (Impact Factor: 5.18). 05/1988; 71(4):575-9

(1) Thaweekul Y, et al., Long term results of anterior colporrhaphy with Kelly plication for the treatment of stress urinary incontinence. J Med Assoc Thai 2004; 87(4): 357-60.

(2) Eriksen BC, et al., Long-term effectiveness of the Burch colposuspension in female urinary stress incontinence, Acta Obstet Gynecol Scand. 1990;69(1):45–50.

(3) Lobel RW and Davis GD, Long-term results of laparoscopic Burch urethropexy. J Am Assoc Gynecol Laparosc. 1997 May;4(3):341–5.

(4) Sohbati S, et al., Comparison Between the Transobturator Tape Procedure and Anterior Colporrhaphy With the Kelly's Plication in the Treatment of Stress Urinary Incontinence: a Randomized Clinical Trial. Nephrourol Mon. 2015 Sep 16; 7(5): e32046. DOI: 10.5812/numonthly.32046.

(5) Kwon E, et al., Success of Pubovaginal Sling in Patients With Stress Urinary Incontinence and Efficacy of Vaginal Sling Release in Patients With Post-Sling Voiding Dysfunction. J Obstet Gynecol Can. 2006 Jun;28(6):519–25.

(6) Lee, D, et al., Long-term outcomes of autologous pubovaginal fascia slings: is there a difference between primary and secondary slings? Neurourol Urodyn. 2015 Jan;34(1):18–23.

(7) Costantini E, et al., Long-term Efficacy of the Transobturator and Retropubic Midurethral Slings for Stress Urinary Incontinence: Single-center Update from a Randomized Controlled Trial. Eur Urol 2014 Sep;66(3):599-601.

(8) Kjolhede P, Long-term efficacy of Burch colposuspension: a 14-year follow-up study. Acta Obstet Gynecol Scand 2005;84:767–72.

(9) Albo ME, et al., Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence. N Engl J Med. 2007 May 24;356(21):2144–55.